8EHQ-1003-15435

MR2700062

September 30, 2003

**SANITIZED OF TSCA Confidential Business Information**



**DELIVERY BY US MAIL**
**CONFIRMATION OF RECEIPT REQUESTED**

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Company Sanitized

SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam,

(" ") is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , a novel experimental pyrethroid insecticide, identified by IUPAC as:



The CAS number for is

has imported solely for R&D testing purposes on behalf of (" ").

first submitted adverse findings (two separate oral toxicity studies with rats, and a single oral toxicity study with mice) on this substance to your Agency on (Document Control Number ). A second report (Document Control Number ) was submitted on (preliminary dose-range finding in non-pregnant rats & preliminary prenatal developmental toxicity in rats). A third report (acute inhalation in rats) was recently submitted on September 22, 2003 (Document Control Number not yet assigned.

recently observed toxicological effects in a four week repeated inhalation toxicity study performed with rats. A summary of the findings are as follows:



Four-week Repeated Inhalation Toxicity Study of in Rats

| | |
|---|---|
| Animals: | Crj:CD-(SD) rats, male & female, 6 weeks old, 8 animals/sex/dose at of initiation of exposure |
| Doses: | Aerial concentrations of 0, 30, 90, and 150 mg/m$^3$<br>Control animals were exposed to air only.<br>The mean actual aerial concentrations chemically were: 26.4, 88.3, and 159 mg/m$^{3)}$ |
| Administration: | repeated dose inhalation (nose-only) via mist for a 4-hour exposure period for a total of 28 days |
| Particle size: | MMAD; 2.64-2.97 μm; GSD 2.14-2.28 |
| Body weight: | males: 186-221 g females: 141-168 g<br>Weight ranges given are those at the initiation of exposure |
| Observation: | Clinical signs of animals were monitored; body weights were taken; food consumption was monitored; hematology and blood biochemistries were performed; organ weights were taken; and necropsies were performed<br><br>Animals were observed for clinical signs and mortality prior to exposure to the test substance; then, daily for the duration of the exposure; just before termination; and, after exposure. |

The NOEL for both sexes of rats in this 4-week repeated inhalation toxicity study was estimated to be lower than 1000 mg/m$^3$ and therefore reportable under TSCA 8(e). Also reportable was a clinical sign (tremor) suggesting neurotoxicological effects from the test substance was observed in the test animals. See summary below for further details.

Summary: No animals died during the conduction of this study. The NOEL for rats of both sexes was estimated to be 88.3 mg/m$^3$.

Occasional generalized tremors were observed in rats of both sexes (2 males and one female) exposed to 150 mg/m$^3$ from day 4 thru day 28.

Additionally, animals the 90 and 150 mg/m$^3$ exposure groups had wet fur around the snout or eyes, but these isolated signs were not considered to be indicative of toxicity, but rather due to the restraint procedure used on the animals.

Substantiation of CBI Claims

We wish to substantiate claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial

development of this compound. Disclosure of this information would harm efforts to commercialize this compound. Please refer to the attached copy of a letter to regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Yours sincerely,

Encl.
cc: